

PATENT COOPERATION TREATY

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REC'D 16 MAY 2006


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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Case 21862 WO		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2004/012655		International filing date (day/month/year) 09.11.2004	Priority date (day/month/year) 19.11.2003	
International Patent Classification (IPC) or national classification and IPC C07D491/04				
Applicant DSM IP ASSETS B.V.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 07.06.2005		Date of completion of this report 13.10.2005		
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Kyriakakou, G Telephone No. +49 89 2399-		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

REC'D	16 MAY 2006
International application No.	
WIPO	PCT/EP2004/012655

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/012655

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-15
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and /or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents

D1:US-A-3250778

D2:US-A-3296275

D3:US-A-3822274

2. Novelty (Art.33(2)PCT)

2.1 The present application relates to a multistep process of preparation of a vitamin B6 precursor 9-acyloxy-1,5-dihydro-8-methylpyrido[3,4-e][1,3]dioxepin derivatives(I) comprising the following steps: a) a diels Alder addition of a 4-methyl-5-alkoxy-oxazole and a 4,7-dihydro-(1,3)-dioxepin in the absence of solvent and catalyst b) addition of an anhydrous organic acid to the product mixture and rearrangement of the Diels-Alder major product and subsequent acylation to the final product (I) The prior art Document 2.2 D1 and D2 disclose a process of preparation of (I) by the same Diels Alder reaction, in the absence of solvent and catalyst, isolation of the intermediate product and obtention of the final product (I) by treatment with either HCl (see D1 claim 1,example 21,column 2 lines71- column 3, line 8) or pyridoxine hydrochloride (see D2, claim1,Example 2). The said documents are therefore prejudicial to the Novelty of the present claims.

The subsequent examination is valid on the condition that new claims are filed which are allowable and which do not contain known subject matter.

3. Inventive step(Art.33(3)PCT)

3.1 The object of the present invention is to provide a process for the preparation of 9-

3.2 The prior art documents D1 and D2,, which disclose same process for the preparation of the same compounds are considered to represent the closest state of the art..

3.3 The experimental data comprised in the application show that the present invention provides a process for the preparation of (I). But the prior art documents describe the same process for the preparation of the same compounds. The optimization of reaction conditions is a common practise for the person skilled in the art.. Consequently the subject matter of the present claims 1-15 does not involve an inventive step. The applicant is therefore kindly requested to submit any relevant evidence for unexpected advantages

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(SEPARATE SHEET)**

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over the prior art, which really qualifies in support of an inventive step.

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-2004058775	15.07.2004	23.12.2003	27.12.2002